UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	

DEFENDANTS' REPLY IN FURTHER IN SUPPORT OF MOTION TO EXCLUDE OPINIONS OF RON NAJAFI, PH.D.

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INTRODUCTION

Plaintiffs' Brief in Opposition to Defendants' Motion to Exclude Opinions of Ron Najafi, Ph.D. ("Opposition" or "Opp.") seeks to insulate Dr. Najafi's opinions from a Rule 702 challenge by simultaneously arguing that the challenge is premature and that his opinions demonstrate that the question of "sameness" or chemical equivalency is common to all class members." (Opp., Dkt. 2090, at 1.) Plaintiffs cannot have it both ways. If Dr. Najafi is not offering any substantive opinions at the class certification stage, then Plaintiffs should withdraw him as an expert. If, however, he seeks to offer expert testimony related to whether Plaintiffs can satisfy the requirements of Rule 23, then his opinions must satisfy Rule 702 and *Daubert.* Plaintiffs' arguments to the contrary are unavailing.

First, Plaintiffs contend that Dr. Najafi is permitted to offer the "class certification opinion" that "NDMA and NDEA contamination is common to all class members." (Opp. at 1.) This opinion does not appear anywhere in Dr. Najafi's written declaration and should be excluded on that basis alone. Further, even if Dr. Najafi had disclosed such an opinion, it would be inadmissible because it constitutes improper narrative testimony.

Second, there is no merit to Plaintiffs' arguments that: (i) Rule 702's requirements do not apply to opinions offered at the class-certification stage; (ii) Defendants have not actually challenged Dr. Najafi's "sameness" opinion; and (iii)

the "sameness" opinion is based on a reliable methodology. The Third Circuit Court of Appeals has made clear that expert opinions offered to demonstrate compliance with Rule 23 must meet the same reliability standards applicable at the merits stage. And, as Defendants explained in their opening memorandum, Dr. Najafi's "sameness" opinion is unsupported and inherently unreliable.

Finally, Plaintiffs appear to concede that the other opinions that Dr. Najafi offers pertaining to "liability" issues (*i.e.*, carcinogenicity of NDMA/NDEA and Defendants' manufacturing practices) are irrelevant to class certification, even though they are included in Dr. Najafi's declaration. (*See* Opp at 1.) As a result, the Court should grant Defendants' request to exclude these opinions for lack of "fit."

ARGUMENT

I. DR. NAJAFI SHOULD BE PRECLUDED FROM OFFERING AN UNDISCLOSED, NARRATIVE OPINION THAT NITROSAMINE EXPOSURE IS "COMMON" TO ALL PROPOSED CLASS MEMBERS.

Plaintiffs attempt to recast Dr. Najafi's seven-page declaration as a single "class certification opinion" that "NDMA and NDEA contamination is common to all class members," (Opp. at 1), but this opinion ***does not appear anywhere*** in Dr. Najafi's declaration. Instead, Plaintiffs invented it in response to Defendants' challenge to the opinions Dr. Najafi actually disclosed in his declaration. It is widely recognized that a party cannot revise or supplement its expert's opinions in legal briefing in an effort to save them from exclusion. *See Tamraz v. Lincoln Elec. Co.*,

620 F.3d 665, 672 (6th Cir. 2010) (rejecting counsel's effort to redefine a proposed expert's opinion in response to a *Daubert* challenge); *In re Rezulin Prod. Liab. Litig*., 369 F. Supp. 2d 398, 407 (S.D.N.Y. 2005) ("The subject of [a *Daubert*] motion is the proposed testimony of experts, not the theories of the lawyers."). For this reason alone, Plaintiffs' arguments should be rejected and Dr. Najafi's purported opinion on "common" issues should be excluded.

Even if Dr. Najafi had opined that "NDMA and NDEA contamination is common to all class members," such an assertion would be based on nothing more than Dr. Najafi's subjective interpretation of Defendants' internal documents and would therefore constitute inadmissible narrative testimony. As courts have repeatedly recognized, an expert cannot "simply rehash[] otherwise admissible evidence about which [he] has no personal knowledge." *In re Mirena IUD Products Liability Litigation*, 169 F. Supp.3d 396, 478, 481 (S.D.N.Y. 2016); *see also, e.g.*, *Rheinfrank v. Abbott Laboratories, Inc.*, No. 1:13-cv-144, 2015 WL 13022172, at *9 (S.D. Ohio Oct. 2, 2015) (precluding expert testimony offered "solely for the purpose of constructing a factual narrative based upon record evidence"), *aff'd*, 680 F. App'x. 369, 2017 WL 680349 (6th Cir. Feb. 21, 2017); *Pritchett v. I-Flow Corp.*, No. 09–cv–02433, 2012 WL 1059948, at *7 (D. Colo. March 28, 2012) (precluding expert witness from "regurgitating factual information that is better presented through introduction of documents or non-expert testimony"); *Hines v. Wyeth*, No.

2:04–0690, 2011 WL 2680842, at *7 (S.D.W. Va. July 8, 2011) (excluding expert testimony "based on her own reading of defendants' internal documents"; jury "is more than capable of reading and summarizing the documents on its own.").

Dr. Najafi has no basis, beyond factual evidence that jurors can interpret, to opine that all of the VCDs at issue were contaminated or that the issue of contamination is "common" to all proposed class members. As a result, any testimony that Dr. Najafi may offer to this effect would not assist the fact-finder. Accordingly, even if Plaintiffs were correct that Dr. Najafi offered this opinion and that it is his only relevant opinion at the class-certification stage, that opinion would be inadmissible.

II. DR. NAJAFI'S "SAMENESS" OPINION SHOULD ALSO BE EXCLUDED.

Despite their efforts to recast Dr. Najafi's testimony, Plaintiffs admit that his opinions are premised on "the fundamental proposition . . . that VCDs with NDMA or NDEA present are not the same as or chemically equivalent to the approved formulations and impurity profiles of the Reference Listed Drugs [("RLDs")], branded Diovan and Exforge." (Opp. at 1.) Indeed, this opinion is central to Plaintiffs' theory of liability and damages in the consumer economic loss and third-party payor cases. As set forth in Defendants' opening memorandum, however, Dr. Najafi's sameness opinion is deeply flawed and unreliable. (*See* Def.'s Mem. of Law ("Def.'s Mem."), Dkt. 2033-1, at 4-12.) Plaintiffs' arguments in response lack merit.

First, Plaintiffs are incorrect that the reliability of Dr. Najafi's sameness opinion and the assumptions underlying it are irrelevant at the class-certification stage. (*See* Opp. at 1 ("[A]t this class certification stage, whether Dr, Najafi is right or wrong is immaterial; his opinions demonstrate a question (e.g., 'sameness' or chemical equivalency) common to all class members.").) Under Rule 702, Plaintiffs are required to demonstrate that Dr. Najafi's opinions are the product of a reliable methodology, *see In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 732 (3d Cir. 1994) (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc*, 509 U.S. 579, 590 (1993)), and the Third Circuit has held that this standard applies equally to experts offered in support of class certification. *See In re Blood Reagents Antitrust Litig*., 783 F.3d 183, 187 (3d Cir. 2015) (finding that expert testimony offered to "demonstrate conformity with Rule 23" must satisfy[y] the standard set out in *Daubert*"). As Defendants have explained, Dr. Najafi's sameness opinion fails this test because it is the product of a demonstrably unreliable methodology, which merits exclusion.

Second, Plaintiffs are wrong that "Defendants present no challenge to the thrust of Dr. Najafi's Declaration in support of class certification, which was 'the presence of the nitrosamine contamination found in the Valsartan products at issue here renders these products as not the same as the Reference Listed Drug, Diovan and/or Exforge.'" (Opp. at 4.) Even a cursory review of Defendants' opening memorandum makes clear that Defendants ***have challenged*** the reliability and

admissibility of that specific opinion. Plaintiffs' opposition brief, which responds to Defendants' arguments in support of excluding such testimony, further confirms this. Accordingly, Plaintiffs' assertions that Defendants have not challenged Dr. Najafi's sameness opinion is false and should be rejected out of hand.

Third, Plaintiffs' substantive response to Defendants' arguments also fails. As Defendants explained in their opening memorandum, Dr. Najafi's sameness opinion is inherently unreliable because both of the assumptions underlying that opinion are demonstrably false.[1] In opining that Defendants VCDs are not the same as the RLDs, Dr. Najafi assumes that: (i) all of Defendants' VCDs contained NDMA or NDEA at an amount above zero; and (ii) none of the RLDs contained NDMA or NDEA at an amount above zero. Neither Dr. Najafi nor Plaintiffs are able to point to any evidence in support of either assumption. To the contrary, as Defendants have noted, samples of the Novartis RLD that were tested by Valisure were shown to contain NDMA. While Plaintiffs insist that the tested Novartis product was a "different drug manufactured with a different process" from the RLD (Opp. at 26), they cite no evidence to support this statement. Nor do Plaintiffs offer any support for their assertion that the Novartis product tested by Valisure was "generic

[1] In addition, Dr. Najafi's opinion is based on a flawed interpretation of the applicable statutes and regulations, and he has provided conflicting testimony regarding Valisure's testing of the RLDs. Because these issues are addressed at length in Defendants' opening memorandum, Defendants do not repeat them here.

valsartan" (*id.*), a position that is belied by the fact that Novartis is not authorized to sell generic valsartan in the United States. These arguments are pure conjecture.

Plaintiffs also cannot refute that Dr. Najafi's assumptions regarding the presence of NDMA and NDEA in the VCDs at issue are contradicted by the FDA's testing, which showed no NDMA and NDEA in certain relevant VCDs. In response, Plaintiffs take the position that such testing is unreliable and irrelevant to Dr. Najafi's opinions. But this argument is directly contrary to Plaintiffs' assertion elsewhere in their opposition that "Dr. Najafi does not need to validate the testing conducted by" Health Canada because it is a regulatory agency, and "Dr. Najafi and other experts in his field reasonably rely on testing conducted by regulatory agencies in forming their opinions, which is all that FRE 703 requires." (Opp. at 18.) Once again, Plaintiffs' arguments are contradictory and self-defeating. Plaintiffs cannot simultaneously argue that data published by Health Canada—which presumably tested non-US product—reliably supports his opinion that none of the RLD contained NDMA or NDEA, while at the same time asserting that FDA's testing of the VCDs at issue is irrelevant to the reliability of his proposed testimony.

Plaintiffs' attacks on the validity of the testing performed with respect to certain Defendants' VCDs are also meritless. For example, Plaintiffs devote three pages of their opposition (Opp. at 21-23) to criticizing Teva's internal testing, which is mentioned once, in a footnote, in Defendants' opening memorandum, (Defs.'

Mem. at 5 n.3).[2] After acknowledging that certain lots of Teva product manufactured using Mylan API did not contain detectable levels of NDMA or NDEA, as documented in FDA's May 21, 2019 News Release, Plaintiffs attempt to downplay those findings on the basis that these lots were not commercialized and never reached any of the proposed class members. (Opp. at 21-22.) But Najafi's opinions are in no way tied to individual lots of product; nor do they turn on whether product containing nitrosamine impurities reached a specific proposed class member. (*See generally* Najafi Rep.) Further, Plaintiffs' assertion that Teva "refused to send the FDA samples of its VCDs until Teva had tested the VCDs and knew what the results would be of the VCDs before deciding which VCDs to send the FDA" is both untrue and unsupported by the internal document Plaintiffs cite for this proposition. (*See* Opp., Ex. R. (email to FDA describing Teva's internal test method validation process and requesting a short extension to complete validation while inquiring if Mylan's documentation that their valsartan process cannot produce NDMA is sufficient for that product).)

Plaintiffs' remaining criticisms of Teva's individual batches and testing are similarly based on flawed assumptions and, in any event, do not undermine

[2] Defendants decline to seriously entertain or address the utterly unsupported, whole-cloth fabrication that Teva – in the midst of recalling all of its product and sending numerous samples to the FDA for testing – chose to perpetrate fraud on the FDA with respect to two single batches submitted for testing.

Defendants' arguments in favor of excluding Dr. Najafi's opinions regarding "sameness."

The same is true of Plaintiffs' attacks on the reliability of Aurobindo's validated test results for its VCDs. Plaintiffs mischaracterize evidence and cherry-pick partial statements to attack the reliability of Aurobindo's validated test results. (Opp. at 19.)[3] But a review of the actual documents shows the dubious nature of Plaintiffs' claims. First, as Aurobindo explains in its opposition to the motion to exclude Dr. Clevenger's opinions, Aurobindo's test method is valid, accurate, and accepted by regulatory bodies across the world, including the FDA. (Clevenger Resp. 8-12, Dkt. 2082.) Indeed, Aurobindo's chemistry manufacturing and controls ("CMC") expert confirmed the accuracy and reliability of the method validation, test results, and Aurobindo's pilot study. (*Id.*) Still, Plaintiff's fault AB for not relying on an ***FDA-recommended*** (as opposed to mandated) test method, which was not even available at the time AB tested its VCDs. But the very document Plaintiffs cite identifying FDA-recommended test methods explicitly points to the European agency for additional published methods. (*See* Opp. at 19 (citing APL-MDL 2875-1296772, Ex. E).) Plaintiffs identify no law or FDA guidance prohibiting Aurobindo from utilizing the EMA's validated method because there is none.

[3] Plaintiffs continue to take an inconsistent position with regard to the reliability of Aurobindo's test results. (*Compare* Dkt. 2047-1 (MTE Clevenger) *with* Dkt. 2013, at 6 (MTC Najafi Materials Resp.).)

Second, Plaintiffs grossly misstate the differences between the FDA's and Aurobindo's test results, which relate to only 9 of the 632 batches Aurobindo tested. Plaintiffs claim "Aurobindo was ***repeatedly*** unable to detect any NDEA in the exact same batches in which the FDA ***repeatedly*** detected NDEA above the allowable limits." (Opp. at 19 (citing APL-MDL-2875-0102832 at 859-61, Dkt. 2047-6) (emphasis added).) What Plaintiffs mean by ***repeatedly***, however, is *twice*. Just ***two*** samples where APL's initial test and retest were both non-detect ("ND"), but the FDA's results detected some amount of NDEA. (*Id.*) And for one of those two samples, the FDA's results were ***below*** FDA's allowable intake ("AI") limit. (Three of the nine FDA results were below the AI, while another had results below and above the AI.) (*Id.*) None of the FDA's results identifies NDMA. (*Id.*) Similarly, Plaintiffs point to the Aberrant Result Investigation Report as an additional basis for unreliability. (Opp. at 19.) But that report reviewed only four batches and concluded, with ***one*** exception, "the results obtained during the initial analysis are comparable with the reanalysis." (*Id.*)

Third, Plaintiffs present this Court with statements they attribute to an Aurobindo consultant that appear critical of Aurobindo's processes, but Plaintiffs' submission is inaccurate at best. For instance, Plaintiffs argue that an Meridan's comments on a draft investigation report undermine the reliability of AB's validated test method. (Opp. at 19 (citing APL-MDL 2875-0135474, Dkt. 2047-7).) But

Plaintiffs ***do not even quote the consultant***. Plaintiffs claim Meridan concluded that "[t]he Aurobindo testing method has poor reproducibility," but cite a non-Meridan employee summary emailed to another employee who then forwards it a second time. (*Compare* APL-MDL 2875-0135474 *with* APL-MDL 2875-2328625, Ex. A.) *Meridan's* actual comment asks Aurobindo, "***Are you saying*** the method has poor reproducibility?" (APL-MDL 2875-2328788, Ex. B (emphasis added).) A question, not a conclusion. Plaintiffs also claim Meridan concluded that "in-house results are consistently much lower than FDA results" but omit both the question ("What action is planned to address this bias?") and the response ("***Aurobindo has established the equivalency between the FDA and Aurobindo method for NDMA & NDEA analysis***.") (*Id.* (emphasis added).) Finally, Plaintiffs leave out the ***if*** of an if/then statement to imply a conclusion instead of a hypothesis: "***If*** site results for nitrosamines are biased low, ***then*** released API and drug product batches may be subject to future recalls." **(**Opp. at 20 (citing APL-MDL 2875-0048768, Dkt. 2047-5).) Thus, Plaintiffs have no basis to claim Meridan concluded that Aurobindo's internal testing is "unreliable." In reality, Meridan was assisting Aurobindo prepare a root cause investigation report, and the comments at most sought to improve the level of detail and analysis in its content and structure.

Plaintiffs appear to claim that because Aurobindo recalled finished dose on two separate dates, all Aurobindo lots should have been recalled. (Opp. at 19-20.)

Setting aside Plaintiffs' unfounded personal aspersions on counsel, the fact that Aurobindo recalled batches on two separate dates does not change the still-true facts that most of Aurobindo's finished dose batches did not contain nitrosamines above the AI, and only a minority of batches were recalled. And it certainly doesn't show that Aurobindo's finished dose contained NDMA. Plaintiffs claim that "Aurobindo continued to release VCDs containing unsafe levels of nitrosamines into the US market . . . based on knowingly inaccurate testing results" (*id.* at 20), but that plainly is both untrue and unfounded. Not only did Aurobindo and Dr. Clevenger confirm reliability of Aurobindo's testing through a validated LC-MS/MS method and pilot study, but Plaintiffs put forth no evidence that Aurobindo believed it was "producing artificially low results" or "selling contaminated VCDs based on knowingly inaccurate testing results." (*Id.* at 20-21.) And as Plaintiffs point out, Aurobindo halted manufacturing all together, but not because it was "unsafe"—Aurobindo discontinued the toluene route in favor of the o-xylene route because the o-xylene route better purges API of nitrosamines. (APL-MDL 2875-2707903, Ex. C.)

Finally, neither FDA nor Aurobindo has detected NDMA above the level of detection in Aurobindo's VCDs, let alone any batches above the AI. (Opp. at 20. Indeed, Plaintiffs' do not identify ***any*** AB batches containing NDMA despite asserting "the FDA detected either NDMA or NDEA ***in every single lot***" of Aurobindo VCDs tested. (*Id.* (emphasis added).) Plaintiffs' attempt to shift the

burden of proof onto Aurobindo to prove that their VCDs did not contain nitrosamines should be rejected. Plaintiffs offer nothing more than speculation that batches other than the recalled batches contained NDMA or NDEA.

III. PLAINTIFFS EFFECTIVELY CONCEDE THAT DR. NAJAFI'S MERITS OPINIONS ARE NOT RELEVANT TO CLASS CERTIFICATION.

As Defendants have explained, Dr. Najafi's liability opinions concerning the carcinogenicity of NDMA and NDEA and Defendants' manufacturing obligations, which he included in his Rule 23 declaration but could not support, have no relevance to Rule 23 and should be excluded. (*See* Def.'s Mem. at 16-18.) Plaintiffs tacitly agree, asserting that "the foundation for the class opinions is provided in the declaration, but that declaration was not intended as a full liability report as that phase has not yet been reached. At a later date, during the liability expert phase, Defendants can seek to challenge Dr. Najafi's merits opinions." (Opp. at 5.)

If Plaintiffs did not intend to offer Dr. Najafi's opinions—other than his one purported class-certification opinion, discussed *supra*—at this stage, Plaintiffs should have either: (i) omitted those opinions from his declaration, or (ii) disclosed their intention to limit his testimony prior to his deposition in order to avoid wasting Defendants' and the Court's time. *See, e.g.*, *Clifton v. State Farm Mut. Auto. Ins. Co.*, No. 18-CV-01231-MSK-STV, 2021 WL 1100403, at *2 (D. Colo. Mar. 23, 2021) ("It is particularly wasteful of the parties' and the Court's time to address

challenges to a particular opinion that no one intends to present"). Indeed, during the general causation phase of this litigation, Plaintiffs affirmatively agreed to limit the scope of Dr. Hecht's at-issue opinions to those pertaining specifically to causation. This occurred well in advance of the witness's deposition, and allowed Defendants to avoid the need to confront Dr. Hecht's so-called merits opinions until the appropriate time. Yet, with respect to Dr. Najafi, Plaintiffs proposed no such limitation at any time prior to his deposition.[4] As a result, Defendants were left no choice but to cross examine Dr. Najafi regarding all of the opinions contained in his Rule 23 declaration.

Because the parties now appear to agree that Dr. Najafi's merits opinions have no relevance to class certification, the Court should exclude them. Likewise, the Court should also preclude Dr. Najafi from offering these opinions at a later stage because, for the reasons stated in Defendants' memorandum, they are unreliable. Plaintiffs should not be permitted a second bite at the apple to cure the defects Defendants have identified (even if that were possible).[5]

[4] During his deposition, both Plaintiffs' counsel and Dr. Najafi suggested that he would issue a supplemental report at a later stage that would expand upon the merits opinions contained in his Rule 23 declaration. (*See* Najafi Dep. 139:3-13; 198:5-12.) But Plaintiffs made no corresponding offer to limit the opinions expressed in his Rule 23 declaration in the manner that Plaintiffs now appear to propose.

[5] If the Court allows Dr. Najafi to submit a supplemental report at a later stage, Defendants reserve the right to cross examine Dr. Najafi on the opinions contained therein, and to further challenge the admissibility of his testimony.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' Motion to Exclude Opinion of Ron Najafi, Ph.D.

Dated: June 16, 2022

Respectfully Submitted:

By: */s/ Clem. C. Trischler*

Clem C. Trischler
Defendants' Executive Committee

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
Clem C. Trischler
Jason M. Reefer
Frank H. Stoy
38th Floor, One Oxford Centre
Pittsburgh, Pennsylvania 15219
Tel: (412) 263-2000
Fax: (412) 263-2001
cct@pietragallo.com
jmr@pietragallo.com
fhs@piettragallo.com

Counsel for Mylan Laboratories, Ltd. and Mylan Pharmaceuticals, Inc.

GREENBERG TRAURIG, LLP
Lori G. Cohen
Victoria Davis Lockard
Steven M. Harkins
Terminus 200
3333 Piedmont Road, N.E., Ste. 2500
Atlanta, Georgia 30305
Tel.: (678) 553-2100

Fax: (678) 553-2386
CohenL@gtlaw.com
LockardV@gtlaw.com
HarkinsS@gtlaw.com

Attorneys for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., and Actavis LLC

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
Jessica D. Miller, *Liaison Counsel for Manufacturer Defendants*
Nina R. Rose
1440 New York Ave., N.W.
Washington, D.C. 20005
Tel.: (202) 371-7000
Fax: (202) 661-0525
jessica.miller@skadden.com
nina.rose@skadden.com

Attorneys for Zhejiang Huahai Pharmaceutical Co, Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare US, LLC

MORGAN, LEWIS & BOCKIUS LLP
John P. Lavelle, Jr.
1701 Market Street
Philadelphia, Pennsylvania 19103
Tel.: (215) 963-5000
Fax: (215) 963-5001
john.lavelle@morganlewis.com

John K. Gisleson
One Oxford Centre, Thirty-Second Floor
Pittsburgh, Pennsylvania 15219

Tel.: (412) 560-3300
Fax: (412) 560-7001
john.gisleson@morganlewis.com

Attorneys for Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC

HILL WALLACK LLP
Eric I. Abraham
William P. Murtha
21 Roszel Road
P.O. Box 5226
Princeton, New Jersey 08543-5226
Tel.: (609) 734-6358
Fax: (609) 452-1888
eabraham@hillwallack.com
wmurtha@hillwallack.com

Attorneys for Hetero Drugs, Ltd. and Hetero Labs Ltd.

KIRKLAND & ELLIS LLP
Devora W. Allon
Alexia R. Brancato
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
Fax: (212) 446-6460
Devora.allon@kirkland.com
Alexia.brancato@kirkland.com

Attorneys for Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.

HARDIN KUNDLA MCKEON & POLETTO
Janet L. Poletto, Esq.
Robert E. Blanton, Jr., Esq.

673 Morris Ave.
Springfield, New Jersey 07081
Tel.: (973) 912-5222
Fax: (973) 912-9212
jpoletto@hkmpp.com
rblanton@hkmpp.com

Attorneys for Hetero USA Inc.

CROWELL & MORING
Andrew D. Kaplan
Daniel T. Campbell
Marie S. Dennis
1001 Pennsylvania Avenue NW
Washington, D.C. 20004
Tel.: (202) 624-1000
Fax: (202) 628-5116
akaplan@crowell.com
dcampbell@crowell.com
mdennis@crowell.com

Attorneys for Cardinal Health, Inc.

ULMER & BERNE LLP
Jeffrey D. Geoppinger
312 Walnut Street, Suite 1400
Cincinnati, OH 45202-2409
Tel.: (513) 698-5038
Fax: (513) 698-5039
jgeoppinger@ulmer.com

Attorneys for AmerisourceBergen Corporation

NORTON ROSE FULBRIGHT US LLP
D'Lesli M. Davis
Ellie K. Norris
2200 Ross Avenue, Suite 3600
Dallas, TX 75201-7932

Tel.: (214) 855-8221
Fax: (214) 855-8200
Dlesli.davis@nortonrosefulbright.com
Ellie.norris@nortonrosefulbright.com

Attorneys for McKesson Corporation

BARNES & THORNBURG LLP
Sarah E. Johnston, *Liaison Counsel for Pharmacy Defendants*
Kristen L. Richer
2029 Century Park East, Suite 300
Los Angeles, CA 90067
Tel.: (310) 284-3798
Fax: (310) 284-3894
Sarah.Johnston@btlaw.com
Kristen.Richer@btlaw.com

Kara Kapke
11 S Meridian St.
Indianapolis, Indiana 46204
Tel: (317) 236-1313
Fax (317) 231-7433
kara.kapke@btlaw.com

Attorneys for CVS Pharmacy, Inc. and Walmart Inc. (incorrectly identified as Walmart Stores, Inc.)

HUSCH BLACKWELL LLP
Matt Knepper
James Spung
190 Carondelet Plaza
Suite 600
St. Louis, Missouri 63105
Tel.: (314) 480-1500
Fax: (314) 480-1505
Matt.knepper@huschblackwell.com
James.spung@huschblackwell.com

Attorneys for Express Scripts, Inc.

LEWIS BRISBOIS BISGAARD & SMITH LLP
Andrew F. Albero
Walter H. Swayze III
550 E. Swedesford Rd., Suite 270
Wayne, PA 19087
Tel.: (215) 977-4058
Fax: (215) 977-4101
Andrew.albero@lewisbrisbois.com
Pete.swayze@lewisbrisbois.com

Attorneys for Camber Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on June 16, 2022, a copy of the foregoing document was served on all counsel of record via CM/ECF.

By: */s/ Clem C. Trischler*
Clem C. Trischler